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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS-OS-20296-30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for revision of the approved information collection assigned OMB control number 0945-0003 scheduled to expire on 12/31/2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or (202) 690-6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting

information, please include the OMB control number 0945-0003 and document identifier HHS-OS-20296-30D for reference.

Information Collection Request Title: Standards for Privacy of Individually Identifiable Health Information, Security Standards for the Protection of Electronic Protected Health Information, and Supporting Regulations Contained in 45 CFR Parts 160 and 164  
OMB No.: 0945-0003

Abstract: The Office for Civil Rights (OCR) is notifying the public of revisions to a previously approved OCR data collection. The revisions reflect certain regulatory modifications to the HIPAA Privacy and Security Rules, pursuant to the Health Information for Economic and Clinical Health (HITECH) Act and the Genetic Information Nondiscrimination Act (GINA), that were finalized in the Omnibus HIPAA Final Rule published on January 25, 2013 (78 FR 5566). These modifications strengthen privacy and security protections for individually identifiable health information used or disclosed by business associates and enhance the rights of individuals with respect to their identifiable health information.

Need and Proposed Use of the Information: The information collection addresses HIPAA requirements related to the use, disclosure, and safeguarding of individually identifiable health information by covered entities affected by the HIPAA Rules. The information is routinely used by covered entities and business associates for treatment, payment, and health care operations. In addition, the information is used for specified public policy purposes, including research, public health, and as required by other laws. The Privacy Rule also ensures that the individuals are able to exercise certain rights with

respect to their information, including the rights to access and seek amendments to their health records and to receive a Notice of Privacy Practices (NPP) from their direct treatment providers and health plans.

Likely Respondents: Respondents include HIPAA covered entities and their business associates, as well as members of the public.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the tables below.

#### Total Estimated Annualized Burden - Hours

##### New Burdens Associated with the Final Rule

Section	Type of Respondent	Number of Respondents	Average Number of Responses per Respondent	Average Burden hours per Response	Total Burden Hours
164.316	Documentation of Security	300,000	1	70/60	350,000

	Rule Policies and Procedures and Administrative Safeguards (business associates)				
164.504	Business Associates Needing to Establish or Modify Business Associate Agreements with Subcontractors	375,000	1	20/60	125,000
164.520	Revision of Notice of Privacy Practices for Protected Health Information (drafting revised language) (health plans)	1,500	1	.111	167
164.520	Dissemination	20,000,000	1	.00333335	66,667

	of Notice of Privacy Practices for Protected Health Information (health plans)				
164.520	Revision of Notice of Privacy Practices (providers)	697,000	1	.11111	77,444
<b>Total</b>					<b>619,278</b>

Ongoing Annual Burdens of Compliance with the Rules

Section	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden hours per Response	Total Burden Hours
160.204	Process for Requesting Exception Determinations (states or persons)	1	1	16	16
164.504	Uses and Disclosures – Organizational	700,000	1	5/60	58,333

	Requirements				
164.508	Uses and Disclosures for Which Individual authorization is required	700,000	1	1	700,000
164.512	Uses and Disclosures for Research Purposes	113,524	1	5/60	9,460
164.520	Notice of Privacy Practices for Protected Health Information (health plans – periodic distribution of NPPs by paper mail)	100,000,000	1	0.25	416,667
164.520	Notice of Privacy Practices for Protected Health Information (health plans –	100,000,000	1	0.167	278,333

	periodic distribution of NPPs by electronic mail)				
164.520	Notice of Privacy Practices for Protected Health Information (health care providers – dissemination and acknowledgement)	613,000,000	1	3/60	30,650,000
164.522	Rights to Request Privacy Protection for Protected Health Information	150,000	1	3/60	7,500
164.524	Access of Individuals to Protected Health Information	150,000	1	3/60	7,500

	(disclosures)				
164.526	Amendment of Protected Health Information (requests)	150,000	1	3/60	7,500
164.526	Amendment of Protected Health Information (denials)	50,000	1	3/60	2,500
164.528	Accounting for Disclosures of Protected Health Information	70,000	1	3/60	5,833
<b>Total</b>					<b>32,143,642</b>

<b>TOTAL HOURS</b>
<b>32,762,920</b>

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Keith A. Tucker

Information Collection Clearance Officer

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